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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/631,189	07/31/2003	Claudia A. Iannotti	10021017-1	1422

7590 03/15/2006

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EXAMINER	
CROW, ROBERT THOMAS	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 03/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/631,189	IANNOTTI ET AL.	
	Examiner	Art Unit	
	Robert T. Crow	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 2.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Preliminary Amendment

The Preliminary Amendment filed 7 July 2004 is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 14-15, and 21-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claims 1-9 are indefinite in line 3 of claim 1, which recites the limitation "a tissue/cell lysate." It is unclear what the"/" symbol represents; e.g., if the symbol means "and" or "or."

2. Claims 5 and 6 are indefinite in line 2 of claim 5, which recites the limitation "animal and plant tissues and/or cells." It is unclear whether "cells" includes those of animal and plant origin or if "cells" constitutes an alternative to animal and plant tissues.

3. Claims 14 and 15 are indefinite in the recitation "said chaotropic agent" in line 1 of each of claims 14 and 15. There is insufficient antecedent basis for this

limitation in the claim. It is suggested that the phrase "said chaotropic agent" be replaced with "said one or more chaotropic agents" in each instance in each claim.

4. Claims 21-22 are indefinite in line 1 of claim 21, which recites the limitation "said elution." There is insufficient antecedent basis for this limitation in the claim. It is suggested that the word "elution" be replaced with "eluting."

5. Claim 23 is indefinite in the recitation "said eluting step." There is insufficient antecedent basis for this limitation in the claim. It is suggested that the word "step" be removed from the claim.

6. Claims 24-37 are indefinite in line 3 of claim 24, which recites the limitation "a tissue/cell lysate." It is unclear what the"/" symbol represents; e.g., if the symbol means "and" or "or."

7. Claims 27-29 are indefinite in line 2 of claim 27, which recites the limitation "said lysis buffer." There is insufficient antecedent basis for this limitation in the claim. It is suggested that the word "said" be replaced with "a."

8. Claims 28 and 29 are indefinite in the recitation "said chaotropic agent" in line 1 of each of claims 28 and 29. There is insufficient antecedent basis for this limitation in the claim. It is suggested that the phrase "said chaotropic agent" be replaced with "said one or more chaotropic agents" in each instance in each claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Colpan et al (U.S. Patent No. 6,383,393 B1, issued 7 May 2002).

Regarding claim 1, Colpan et al teach the method of preparing a sample substantially free of genomic DNA (e.g., a method for purification and separation of nucleic acid mixtures; Abstract, lines 1-2), comprising the following steps: forming a tissue/cell lysate from a biological sample (Example 1, column 7); contacting a pre-filtration column with said lysate (column 7, lines 30-36), wherein said pre-filtration column comprises a filter material, wherein said filter

material has at least one layer of glass (column 7, lines 30-36); and collecting the effluent from said column, wherein said effluent is substantially free of said genomic DNA (e.g., plasmid DNA substantially free of genomic DNA; Example 1, column 8, lines 16-20).

Regarding claim 2, Colpan et al teach the method of claim 1, wherein said lysate is formed employing a lysis buffer comprising a chaotropic reagent (column 3, lines 20-25).

Regarding claim 3, Colpan et al teach the method of claim 2, wherein said chaotropic agent is guanidine hydrochloride (Example 1, column 7, lines 64-66).

Regarding claim 4, Colpan et al teach the method of claim 2, wherein said chaotropic agent is at a concentration ranging from about 0.5M to 5.0M (Example 1, column 7, lines 64-66).

Regarding claim 5, Colpan et al teach the method of claim 1, wherein said biological sample is tissues (column 5, lines 64-67).

Regarding claim 6, Colpan et al teach the method of claim 5, wherein said animal tissues are blood (column 5, lines 64-67).

Regarding claim 7, Colpan et al teach the method of claim 1, wherein said filter material has a particle retention ranging from about 0.1 microns to about 10 microns (e.g., the glass has a pore size of 1 micron; column 6, lines 60-67).

Regarding claim 8, Colpan et al teach the method of claim 1, wherein said filter material has a thickness ranging from about 50 microns to about 2000 microns (column 6, lines 60-67).

2. Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Colpan et al (U.S. Patent No. 6,383,393 B1, issued 7 May 2002) as defined by the Aldrich Catalog (Aldrich Chemical Company, Milwaukee, WI, page T289 (1998/1999)).

Regarding claim 9, Colpan et al teach the method of claim 1. Colpan et al also teach the use of glass fibers (column 6, lines 60-67). Aldrich teaches glass fibers in 2 in diameter bundles that are 22 feet long, weighing 454 g (page T281, column 2, paragraph 1). A filter layer having a 2 in (5.08 cm) diameter has an area of 0.00203 m^2; therefore, a filter layer having a 2 in diameter and a length (i.e., the thickness of the layer in a column) of 0.25 in has a specific weight of 212 g/m^2, thereby meeting the limitation of the claim. Further, it is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not posses characteristic relied on" (205 USPQ 594, second column, first full paragraph). In the instant case, Applicant must provide proof that the specific

weight ranging from about 75 g/m^2 to about 300 g/m^2 as claimed represents a new and non-obvious property beyond what is commonly known in the art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 10-17 and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haj-Ahmad (U.S. Patent No. 6,177,278 B1, issued 23 January 2001) in view of Colpan et al (U.S. Patent No. 6,383,393 B1, issued 7 May 2002).

Regarding claim 10, Haj-Ahmad teaches a method of isolating a nucleic acid from a sample matrix comprising the following steps: forming a sample preparation by disrupting cells contained in said sample matrix using a lysis buffer (column 3, lines 19-24); contacting a silicon carbide column with said sample preparation (column 3, lines 38-41); and eluting said nucleic from said silicon carbide column (column 3, lines 41-55). While Haj-Ahmad teaches lysing of cells (column 3, lines 19-24), Haj-Ahmad is silent with respect to tissues.

However, Colpan et al teach a method for the isolating nucleic acid from a sample matrix (Abstract, lines 1-2) comprising using a column to purify the nucleic acid (column 7, lines 30-36) after forming a lysate from a biological sample including all tissues (column 5, lines 64-67) with the added benefit of allowing the study of tumors (column 11, lines 5-6).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was claimed to have modified the method of Haj-Ahmad to include the lysing of tissues as taught by Colpan et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because the modification would have resulted in allowing the study of tumors as explicitly taught by Colpan et al (column 11, lines 5-6).

Regarding claim 11, the method of claim 10 is discussed above. Haj-Ahmad also teaches the method wherein said nucleic acid is RNA (Abstract, line 10).

Regarding claim 12, the method of claim 10 is discussed above. Colpan et al also teach DNA digestion (column 8, lines 61).

Regarding claim 13, the method of claim 10 is discussed above. Haj-Ahmad also teaches the method wherein chaotropic agents are used in the sample preparation step (Abstract, line 5).

Regarding claim 14, the method of claim 13 is discussed above. Haj-Ahmad also teaches the method wherein the chaotropic reagent is guanidine hydrochloride (column 5, lines 14-18).

Regarding claim 15, the method of claim 13 is discussed above. Haj-Ahmad also teaches the method wherein said chaotropic reagent is at a concentration ranging from about 0.5 M to about 5.0 M (column 5, lines 14-18).

Regarding claim 16, the method of claim 10 is discussed above. Haj-Ahmad also teaches the method wherein one or more organic solvent binding enhancers are included in the sample preparation step (column 2, lines 47-48).

Regarding claim 17, the method of claim 16 is discussed above. Haj-Ahmad also teaches the method wherein said enhancer is ethanol (column 2, lines 47-48).

Regarding claim 19, the method of claim 13 is discussed above. Colpan et al also teach β-mercaptoethanol buffers (column 11, line 65).

Regarding claim 20, the method of claim 10 is discussed above. Haj-Ahmad also teaches the method wherein said lysis buffer has a pH in the range from about 4 to about 8 (column 4, lines 40-50).

Regarding claim 21, the method of claim 10 is discussed above. Haj-Ahmad also teaches the method wherein said elution is performed using EDTA buffer (e.g., TE buffer; column 4, lines 40-49).

Regarding claim 22, the method of claim 21 is discussed above. While Haj-Ahmad teaches an elution buffer (e.g., TE buffer, column 4, lines 40-49), Haj-Ahmad is silent with respect to the pH of the elution buffer. However, TE buffers ranging in pH from about 4 to about 9 were well known in the art at the time the invention was claimed, as evidenced by the teaching of Colpan et al, wherein a nucleic acid elution TE buffer with a pH of 8.5 is disclosed (Example 1; column 8, lines 14-16).

2. Claims 10 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colpan et al (U.S. Patent No. 6,383,393 B1, issued 7 May 2002) and Haj-Ahmad (U.S. Patent No. 6,177,278 B1, issued 23 January 2001) in view of Kimura et al (U.S. Patent No. 3,933,984, issued 20 January 1976).

Regarding claim 18, Haj-Ahmad teaches a method of isolating a nucleic acid from a sample matrix comprising the following steps: forming a sample preparation by disrupting cells contained in said sample matrix using a lysis buffer (column 3, lines 19-24); contacting a silicon carbide column with said sample preparation (column 3, lines 38-41); and eluting said nucleic from said silicon carbide column (column 3, lines 41-55). While Haj-Ahmad teaches lysing of cells (column 3, lines 19-24), Haj-Ahmad is silent with respect to tissues.

However, Colpan et al teach a method for the isolating nucleic acid from a sample matrix (Abstract, lines 1-2) comprising using a column to purify the nucleic acid (column 7, lines 30-36) after forming a lysate from a biological sample including all tissues (column 5, lines 64-67) with the added benefit of allowing the study of tumors (column 11, lines 5-6).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was claimed to have modified the method of Haj-Ahmad to include the lysing of tissues as taught by Colpan et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because the modification would have resulted in allowing the study of tumors as explicitly taught by Colpan et al ([column 11, lines 5-6]; i.e., the method of claim 10).

Colpan et al also teach fritted columns with layers adjacent to frits (column 7, lines 21-30). While neither Haj-Ahmad nor Colpan et al specifically

teaches silicon carbide whiskers, the courts have held that "where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device." (*Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830, 225 USPQ 232 (1984)). See MPEP 2144.04, IVA. Kimura et al teach that the term "whisker," as applied to metal carbides, refers to needle-like single crystals having a diameter of a few microns and a length of several millimeters (column 1, lines 11-22), thereby establishing the term "whisker" as a mere descriptor of the dimensions of the silicon carbide particles.

3. Claims 24-31 and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colpan et al (U.S. Patent No. 6,383,393 B1, issued 7 May 2002) in view of over Haj-Ahmad (U.S. Patent No. 6,177,278 B1, issued 23 January 2001).

Regarding claim 24, Colpan et al teach the method of preparing a sample substantially free of genomic DNA (e.g., a method for purification and separation of nucleic acid mixtures; Abstract, lines 1-2), comprising the following steps: forming a tissue/cell lysate from a biological sample (column 2, line 65); contacting a pre-filtration column with said lysate (column 7, lines 30-36),

wherein said pre-filtration column comprises a filter material, wherein said filter material has at least one layer of glass (column 7, lines 30-36); and collecting the effluent from said column, wherein said effluent is substantially free of said genomic DNA (e.g., plasmid DNA, genomic DNA and RNA are separated and purified). While Colpan et al also teach use of the nucleic acid subsequent reactions (column 4, lines 15-21), Colpan et al are silent with respect to silicon carbide columns.

However, Haj-Ahmad teaches a method of isolating a nucleic acid from a sample matrix comprising the following steps: forming a sample preparation by disrupting cells contained in said sample matrix using a lysis buffer (column 3, lines 19-24); contacting a silicon carbide column with said sample preparation (column 3, lines 38-41); and eluting said nucleic from said silicon carbide column (column 3, lines 41-55) with the added benefit that silicon carbide is an affordable and readily available substance available in a variety of grades, each grade having a different capacity for binding nucleic acids (column 2, lines 30-35).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was claimed to have modified the method of isolation as taught by Colpan et al by using a silicon carbide column as taught by Haj-Ahmad with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because the modification would have resulted in a column composed of an affordable and readily

available substance available in a variety of grades, each grade having a different capacity for binding nucleic acids as explicitly taught by Haj-Ahmad (column 2, lines 30-35).

Regarding claim 25, the method of claim 24 is discussed above. Haj-Ahmad also teaches the method wherein said nucleic acid is RNA (Abstract, line 10).

Regarding claim 26, the method of claim 24 is discussed above. Colpan et al also teach DNA digestion (column 8, lines 61).

Regarding claim 27, the method of claim 24 is discussed above. Colpan et al also teach the method wherein chaotropic agents are used in the sample preparation step (column 3, lines 20-25).

Regarding claim 28, the method of claim 27 is discussed above. Colpan et al also teach the method wherein the chaotropic reagent is guanidine hydrochloride (Example 1, column 7, lines 64-66).

Regarding claim 29, the method of claim 27 is discussed above. Colpan et al also teach the method wherein said chaotropic reagent is at a concentration ranging from about 0.5 M to about 5.0 M (Example 1, column 7, lines 64-66).

Regarding claim 30, the method of claim 24 is discussed above. Colpan et al also teach the method wherein one or more organic solvent binding enhancers are included in the sample preparation step (column 5, lines 25-28).

Regarding claim 31, the method of claim 30 is discussed above. Colpan et al also teach the method wherein said enhancer is ethanol (column 5, lines 25-28).

Regarding claim 33, the method of claim 24 is discussed above. Colpan et al also teach β-mercaptoethanol buffers in the sample preparation step (column 11, line 65).

Regarding claim 34, the method of claim 24 is discussed above. Colpan et al also teach the method wherein said lysis buffer has a pH in the range from about 4 to about 8 (column 11, lines 63-65).

Regarding claim 35, the method of claim 24 is discussed above. Haj-Ahmad also teaches the method wherein said elution is performed using EDTA buffer (e.g., TE buffer; column 4, lines 40-49).

Regarding claim 36, the method of claim 35 is discussed above. While Haj-Ahmad teaches an elution buffer (e.g., TE buffer, column 4, lines 40-49), Haj-Ahmad is silent with respect to the pH of the elution buffer. However, TE buffers ranging in pH from about 4 to about 9 were well known in the art at the time the invention was claimed, as evidenced by the teaching of Colpan et al, wherein a nucleic acid elution TE buffer with a pH of 8.5 is disclosed (Example 1; column 8, lines 14-16).

4. Claims 24 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colpan et al (U.S. Patent No. 6,383,393 B1, issued 7 May 2002) in view of

over Haj-Ahmad (U.S. Patent No. 6,177,278 B1, issued 23 January 2001) in view of Kimura et al (U.S. Patent No. 3,933,984, issued 20 January 1976).

Regarding claim 32, Colpan et al teach the method of preparing a sample substantially free of genomic DNA (e.g., a method for purification and separation of nucleic acid mixtures; Abstract, lines 1-2), comprising the following steps: forming a tissue/cell lysate from a biological sample (column 2, line 65); contacting a pre-filtration column with said lysate (column 7, lines 30-36), wherein said pre-filtration column comprises a filter material, wherein said filter material has at least one layer of glass (column 7, lines 30-36); and collecting the effluent from said column, wherein said effluent is substantially free of said genomic DNA (e.g., plasmid DNA, genomic DNA and RNA are separated and purified). While Colpan et al also teach use of the nucleic acid subsequent reactions (column 4, lines 15-21), Colpan et al are silent with respect to silicon carbide columns.

However, Haj-Ahmad teaches a method of isolating a nucleic acid from a sample matrix comprising the following steps: forming a sample preparation by disrupting cells contained in said sample matrix using a lysis buffer (column 3, lines 19-24); contacting a silicon carbide column with said sample preparation (column 3, lines 38-41); and eluting said nucleic from said silicon carbide column (column 3, lines 41-55) with the added benefit that silicon carbide is an affordable

and readily available substance available in a variety of grades, each grade having a different capacity for binding nucleic acids (column 2, lines 30-35).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was claimed to have modified the method of isolation as taught by Colpan et al by using a silicon carbide column as taught by Haj-Ahmad with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because the modification would have resulted in a column composed of an affordable and readily available substance available in a variety of grades, each grade having a different capacity for binding nucleic acids as explicitly taught by Haj-Ahmad ([column 2, lines 30-35]; i.e., the method of claim 24).

Colpan et al also teach fritted columns with layers adjacent to frits (column 7, lines 21-30). While neither Haj-Ahmad nor Colpan et al specifically teaches silicon carbide whiskers, the courts have held that "where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device." (*Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830, 225 USPQ 232 (1984)). See MPEP 2144.04, IVA. Kimura et al teach that the term "whisker," as applied to metal carbides, refers to needle-like single crystals

having a diameter of a few microns and a length of several millimeters (column 1, lines 11-22), thereby establishing the term "whisker" as a mere descriptor of the dimensions of the silicon carbide particles.

5. Claims 10, 23, 24, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colpan et al (U.S. Patent No. 6,383,393 B1, issued 7 May 2002) and Haj-Ahmad (U.S. Patent No. 6,177,278 B1, issued 23 January 2001) in view of Crossway et al (U.S. Patent No. 4,996,144, issued 26 February, 1991).

Regarding claim 23, Haj-Ahmad teaches a method of isolating a nucleic acid from a sample matrix comprising the following steps: forming a sample preparation by disrupting cells contained in said sample matrix using a lysis buffer (column 3, lines 19-24); contacting a silicon carbide column with said sample preparation (column 3, lines 38-41); and eluting said nucleic from said silicon carbide column (column 3, lines 41-55). While Haj-Ahmad teaches lying of cells (column 3, lines 19-24), Haj-Ahmad is silent with respect to tissues.

However, Colpan et al teach a method for the isolating nucleic acid from a sample matrix (Abstract, lines 1-2) comprising using a column to purify the nucleic acid (column 7, lines 30-36) after forming a lysate from a biological sample (column 2, line 65) including all tissues (column 11) with the added benefit of allowing the study of tumors (column 11, lines 5-6).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was claimed to have modified the method of Haj-Ahmad to include the lysing of tissues as taught by Colpan et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because the modification would have resulted in allowing the study of tumors as explicitly taught by Colpan et al ([column 11, lines 5-6]; e.g., the method of claim 10). While Colpan et al also teach DNA digestion (column 8, lines 61), neither Haj-Ahmad nor Colpan et al teach digestion with DNAse.

However, Crossway et al teach a method of purification of nucleic acids (e.g., RNA; Abstract, lines 3-5) using digestion with DNAse with the added benefit of allowing differential detection of RNA only (column 5, lines 60-63).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was claimed to have modified the method of isolating a nucleic acid as taught by Colpan et al and Haj-Ahmad with the DNAse treatment as taught by Crossway et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because the modification would have resulted in allowing differential detection of RNA only as explicitly taught by Crossway et al (column 5, lines 60-63).

Regarding claim 37, Colpan et al teach the method of preparing a sample substantially free of genomic DNA (e.g., a method for purification and separation of nucleic acid mixtures; Abstract, lines 1-2), comprising the following steps: forming a tissue/cell lysate from a biological sample (column 2, line 65); contacting a pre-filtration column with said lysate (column 7, lines 30-36), wherein said pre-filtration column comprises a filter material, wherein said filter material has at least one layer of glass (column 7, lines 30-36); and collecting the effluent from said column, wherein said effluent is substantially free of said genomic DNA (e.g., plasmid DNA, genomic DNA and RNA are separated and purified). While Colpan et al also teach use of the nucleic acid subsequent reactions (column 4, lines 15-21), Colpan et al are silent with respect to silicon carbide columns.

However, Haj-Ahmad teaches a method of isolating a nucleic acid from a sample matrix comprising the following steps: forming a sample preparation by disrupting cells contained in said sample matrix using a lysis buffer (column 3, lines 19-24); contacting a silicon carbide column with said sample preparation (column 3, lines 38-41); and eluting said nucleic from said silicon carbide column (column 3, lines 41-55) with the added benefit that silicon carbide is an affordable and readily available substance available in a variety of grades, each grade having a different capacity for binding nucleic acids (column 2, lines 30-35).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was claimed to have modified the method of isolation as taught by Colpan et al by using a silicon carbide column as taught by Haj-Ahmad with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because the modification would have resulted in a column composed of an affordable and readily available substance available in a variety of grades, each grade having a different capacity for binding nucleic acids as explicitly taught by Haj-Ahmad ([column 2, lines 30-35]; e.g., the method of claim 24). While Colpan et al also teach DNA digestion (column 8, lines 61), neither Haj-Ahmad nor Colpan et al teach digestion with DNAse.

However, Crossway et al teach a method of purification of nucleic acids (e.g., RNA; Abstract, lines 3-5) using digestion with DNAse with the added benefit of allowing differential detection of RNA only (column 5, lines 60-63).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was claimed to have modified the method of isolating a nucleic acid as taught by Colpan et al and Haj-Ahmad with the DNAse treatment as taught by Crossway et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because the modification would have resulted in allowing

differential detection of RNA only as explicitly taught by Crossway et al (column 5, lines 60-63).

Statutory Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 25 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 13 of copending Application No. 10/914,920. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Nonstatutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is

appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 24, 30 and 32 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 7-12 of copending Application No. 10/914,920 in view of Haj-Ahmad (U.S. Patent No. 6,177,278 B1). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods of purification of RNA using pre-filtration columns having a glass or borosilicate layer and contacting the effluent with a second column that allows separation of RNA. Claims 1 and 7-12 of the '920 application are drawn to an RNA isolation column, but are silent with respect to silicon carbide.

However, Haj-Ahmand teaches purification of RNA Abstract, line 10) using silicon carbide particles (Abstract, line 4) with the added advantage that silicon carbide is an economical medium for use in purification of nucleic acids (column 2, lines 24-38).

It would therefore have been obvious to modify the claims of the '920 application with the silicon carbide particles as taught by Haj-Ahmad with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because the modification would have resulted in use of an economically efficient medium for use in purification of nucleic acids as explicitly taught by Haj-Ahmad (column 2, lines 24-38).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

2. Claims 24 and 25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 19 of copending Application No. 10/693,428 in view of Haj-Ahmad et al (U.S. Patent No. 6,177,278 B1). Both sets of claims are drawn to forming a tissue/cell lysate, contacting a prefiltration column with said lysate, wherein said prefiltration column comprises a filter material with at least one layer of glass or borosilicate fiber, collecting an effluent from said column, contacting the effluent with a

second column, and collecting the nucleic acid from said second column. Claim 19 of the '428 application is drawn to an RNA isolation column, but is silent with respect to silicon carbide.

However, Haj-Ahmand teaches purification of RNA Abstract, line 10) using silicon carbide particles (Abstract, line 4) with the added advantage that silicon carbide is an economical medium for use in purification of nucleic acids (column 2, lines 24-38).

It would therefore have been obvious to modify the claims of the '428 application with the silicon carbide particles as taught by Haj-Ahmad with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because the modification would have resulted in use of an economically efficient medium for use in purification of nucleic acids as explicitly taught by Haj-Ahmad (column 2, lines 24-38).

This is a provisional obviousness-type double patenting rejection.

Conclusion

No claim is allowed.

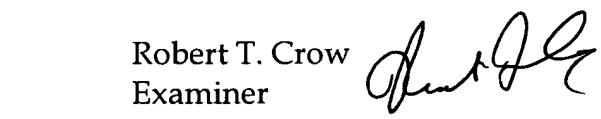
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert T. Crow whose telephone

number is (571) 272-1113. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert T. Crow
Examiner
Art Unit 1634



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PRIMARY EXAMINER